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| GAMBRO, INC<br>PATENT DEPARTMENT<br>10810 W COLLINS AVE<br>LAKEWOOD, CO 80215 |             |                      | EXAMINER<br>MENON, KRISHNAN S |                        |
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/708,774  
Filing Date: March 24, 2004  
Appellant(s): DANNENMAIER ET AL.

**MAILED  
OCT 11 2007  
GROUP 1700**

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John R. Merklings  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 9/10/07 appealing from the Office action mailed 1/18/07.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

|              |       |            |
|--------------|-------|------------|
| 5882516      | GROSS | MARCH 1999 |
| 2003/0102264 | POPE  | JUNE 2003  |

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,4,5,16, and 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al (US 5,882,516).

Claims 1,4,5: Gross teaches a hollow fiber membrane cartridge (figure 1) having two internal compartments (20 and 22) separated by a common wall (18), each compartment having hollow fibers (42), with inlets and outlets (34,36,38,40 and 44), and one of the longitudinal shell portion forming the smaller of the two compartments has less than half the perimeter. Housing is tubular, and the perimeter is the circumference.

Claim 16 and 19-21: the functional arrangement of the filter in figure 1 and 2 are the smaller side is for ultrafiltration and the larger side is for dialysis – see column 2 lines 33-44. The exterior surface of the hollow fibers of the smaller chamber is in fluid communication with the interior side of the hollow fibers of the larger chamber.

Claim 22-24: the cartridge is assembled as claimed – see figures 1 and 2.

2. Claims 6,10-12 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gross.

Claim 6 recites longitudinal seams in the shell, and claims 10-12 recite the assembly process of the shell. However, these limitations are purely for the process of making the device, which do not other wise make any structural difference to the finished device claimed. Gross does not disclose how the shell portions are joined together to form the shell. However, as can be seen from the figures of Gross, the partition wall (18) has to be joined to the tubular wall 12 of the shell, which requires at least two longitudinal joints along the length of the shell. In any case, the longitudinal seams and the claim language of claims 10-12 of components "being configured to join" are related to the process of assembly. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re *Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross

Claims 2 and 3 recite the perimeter of the shell portions as less than a third or a quarter of the housing, which is not specifically taught by the reference. However, the size of the shell would depend on the size of the filter to be accommodated, which would depend on the quantity of fluid to be processed, and one of ordinary skill in the art could optimize this size for the intended purpose. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)

4. Claims 14,15,36,38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross as applied to claim 1 above, and further in view of Pope et al (US 2003/0102264).

Claims differ from the teaching of Gross in the recitation of the longitudinal shell portions having material with different refractive index, and particularly, polycarbonate and polypropylene. Applicant's stated purpose for the different refractive index in the materials is for monitoring the weld quality between the two shell portions, which is only

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a manufacturing step, and does not appear to otherwise contribute to the patentability of the product. Since no other criticality appears to be disclosed for the choice of the materials, and because applicant elected 'adhesive' as the means for joining the shell portions as opposed to welding, the choice of the refractive index of the material, or the choice of polypropylene and polycarbonate, are not patentable limitations. Pope teaches that both polypropylene and polycarbonate can be used for making the dialyzer shell, with polycarbonate being better for visibility, whereas polypropylene is cheaper (see paragraph 20). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Pope in the teaching of Gross to have either, or a combination, of polypropylene and polycarbonate. One would use polycarbonate over polypropylene for the parts that require transparency, such as the part of the shell where blood flows through the membrane, so that any blood leak is clearly visible, and polypropylene for others to reduce the cost.

*Response to Arguments submitted in response to the non-final action:*

Applicant's arguments filed 12/28/06 have been fully considered but they are not persuasive.

Regarding the Gross reference, the Examiner agrees that Gross does not expressly state the argued limitation. However, if one looks at the figures of Gross, it is very clear that the smaller shell portion would 'describe' a smaller portion of the perimeter of the housing (which is the circumference of the cylindrical housing). Now, the perimeter of the housing 'described' by the shell portions would be about half of the

circumference, if the two portions were of about the same size. Since one is less than the other, the smaller one would have less than half of the circumference of the housing. Since the reference does not specifically limit the sizes of the two modules within the housing, even claims 2 and 3 would be anticipated by the reference. Applicant also does not attribute any significance to this limitation for consideration towards patentability.

Regarding claims 6 and 10-12, the limitations that would make the method of assembly easier is not patentable in the product claim. They may be patentable when recited in the method claims. In re Thorpe is properly applied. In claims 10-12, the cited limitations are for the parts of the product before assembly, what is claimed is an assembled product. The assembled product must be structurally discernable and non-obvious from the prior art to overcome the prior art; not the parts that go into the assembly.

Arguments against the optimization of the size for claims 2 and 3 are not convincing. One could of course have any size shell and fit any size bundle in it, but normally one would be inclined to fit a smaller bundle in a smaller shell; there is nothing inventive about it.

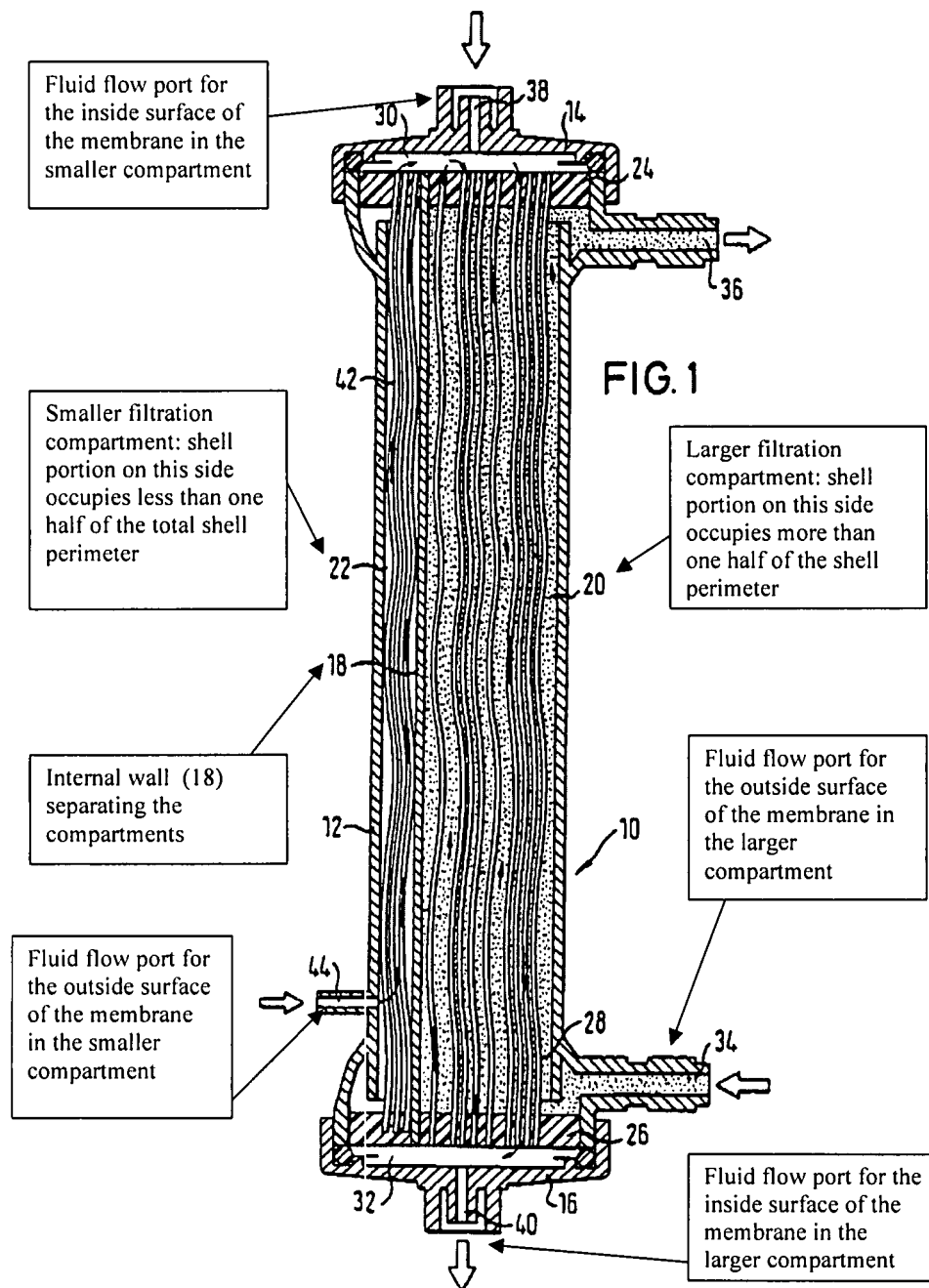
With respect to the Pope reference, adhesive and welding: applicant voluntarily elected adhesive, the Examiner did not force it up on the applicant. However, had applicant elected 'welding' as the means for joining, even then the state of the product claims would not have been any different. A structural limitation which is distinguishable from the prior art and which has advantages in manufacturing **may be** patentable;



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however, the instant claims do not recite such a structural limitation that can be distinguished from that of the prior art, or the combination of prior arts. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

**(10) Response to Argument**



**Figure 1** of the Gross reference illustrated with limitations of claim 1.

Claim 1 (Sections 102 and 103):

Appellant argues:

"Claim 1 specifies that the housing comprises "at least two longitudinally extending shell portions, one of said longitudinally extending shell portions of the housing describing less than one half of the perimeter of said housing". This structure is not shown or suggested in Gross, even though the two modules are of different sizes."

As shown in the figure 1 of the reference above, the internal wall (18) divides the shell of the cartridge in to two compartments. The compartment on the left, identified as (22) is distinctly smaller than the compartment on the right, identified as (20). If one were to draw a cross-section of the picture above, one could clearly see that the perimeter of the shell portion (22) would be smaller than the perimeter of the shell portion (20). Thus the reference anticipates claim 1.

Rest of the argument presented under Claim 1 are not commensurate in scope with the claim or the rejection.

Claim 6 (Sections 102 and 103):

Appellant's arguments are not persuasive; they are also not commensurate in scope with the rejection. Claim 6 recites at least two seams forming the joint between the shell portions, which is a part of the process of making. The finished shell is tubular and the reference anticipates it. Even if the finished shell is considered as structurally different because of a visible seam, it is still not patentable – it would be obvious to one of ordinary skill, because welded tubes are well known.

Claims 10,11 and 12 (Sections 102 and 103):

Appellant recites the components that are configured to be joined to make the shell in these claims. Since claim 1 is for a finished product, the limitations of these claims were considered as part of the process of making. Otherwise, these claims would be indefinite, since claim 1 recites a finished product, and claims 10-12 recite the unfinished raw materials (or components). 'Configured to join ...' is still unfinished. Arguments submitted by the appellant for claims 11 and 12 are all about process of making; claims are for the product.

Claim 2, Section 103:

Appellant's argument that the sizes of the shell portions are impossible to be derived by optimization is not convincing. The shell portions are identified above in the rejection as well as by the illustration of figure 1 of Gross above. The size of the smaller and the larger shell portions would depend on the counts of the hollow fibers present in them, which is obvious. Now, appellant's argument as directed at the shell portions defined in appellant's specification is not commensurate in scope with the claim and the rejection, because the claims read on the reference. Moreover, appellant's shell portions also can be sized by optimization – the larger portion should be large enough to hold the fiber bundles during assembly.

Claim 14, section 103:

The added limitation in claim 14 is two materials with different refractive index, which appellant discloses as required for observing the weld integrity. However, the elected claims are for joint using an adhesive, and therefore, the refractive index limitation does not add any particular feature to the finished product claim, and, therefore, is not patentable.

Pope compares polypro and polycarbonate for similar use, but does not specifically teach having both polypro and polycarbonate together as applicant claims. Applicant would have an advantage to judge the weld quality by using materials of two different refractive index, if the process of making is by welding, and the corresponding ***process claims*** could overcome the prior arts considered (However, patentability in this case requires further consideration). But the claims presented are for the apparatus, and the method of joining is by using an adhesive. The inside wall serves no other purpose than a partition for a compartment, and no structural difference can be discerned in the finished product when compared to Gross. The examiner believes that the apparatus claim 14 is not patentable as is; and not patentable even if the welded joint were recited in the claim. Appellant had elected the adhesive joint in response to the restriction requirement.


#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

  
Krishnan S Menon  
Primary Examiner  
Art Unit 1723  
10/9/07

Conferees:

  
David Sample, SPE

  
Romulo Delmendo